PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Watling *et al.*	)
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Application No.: 10/523,349	)
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Filed: 08/23/2005	)
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Group Art Unit: 1796	)
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Examiner: Marc S. Zimmer	)
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BIOMEDICAL COMPOSITIONS	)
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DECLARATION OF TIMOTHY CHARLES HUGHES UNDER 37 C.F.R. § 1.132
("HUGHES DECLARATION I")

I, Timothy Charles Hughes, of Bayview Avenue, Clayton, Victoria 3168, a principal research scientist, being duly warned hereby declare and state:

1. I am employed by Commonwealth Scientific and Industrial Research Organisation in the Molecular and Health Technologies Division as a principal research scientist. I was awarded a Doctor of Philosophy in 1997 in the field of Chemistry.

2. I have read and am familiar with the specification of U.S. patent application no. 10/523,349 (**"the Present Application"**), and the International patent application from which it derives, PCT/AU2003/000958. I supervised, and was involved in, the synthesis and testing of the polysiloxane macromonomers and cured polymers which led to, and are used to exemplify, the Present Applications. I am an inventor, and my employer is assignee, of the Present Application but I was not primarily responsible for preparing the patent specification.

3. I have recently become aware of obvious errors in the Present Application with respect to the nomenclature used to characterise moduli of the polymers. These obvious errors are:

(a) at page 10, lines 9-10, where the sentence "This E modulus of the polymer of the invention may be measured by a Micro Fourier Rheometer" should read "This shear modulus of the polymer of the invention may be measured by a Micro Fourier Rheometer";

(b) at page 10, lines 11-13, where the sentence "For a lens application of this invention, the E modulus measured by a Micro Fourier Rheometer in this way is ..." should read "For a lens application of this invention, the shear modulus measured by a Micro Fourier Rheometer in this way is ...";

(c) at page 17, lines 6-7, where the sentence "The Young's modulus of the cured polymer was measured by MFR as being 27 kPa" should read "The shear modulus of the cured polymer was measured by MFR as being 27 kPa";

(d) at page 18, lines 21-22, where the sentence "The Young's modulus of the cured polymer was measured by MFR as being 4.6 kPa" should read "The shear modulus of the cured polymer was measured by MFR as being 4.6 kPa";

(e) at page 19, lines 23-24, where the sentence "The Young's modulus of the cured polymer was measured by MFR as being 1.5 kPa." should read "The shear modulus of the cured polymer was measured by MFR as being 1.5 kPa";

(f) at page 20, lines 16-17, where the sentence "The Young's modulus of the cured polymer was measured by MFR as being 0.3 kPa" should read "The shear modulus of the cured polymer was measured by MFR as being 0.3 kPa";

(g) at page 21, lines 9-10, where the sentence "The Young's modulus of the cured polymer was measured by MFR as being 0.3 kPa" should read "The shear modulus of the cured polymer was measured by MFR as being 0.3 kPa";

(h) at page 21, lines 18-19, where the sentence "The Young's modulus of the cured polymer was measured by MFR as being 4.0 kPa" should read "The shear modulus of the cured polymer was measured by MFR as being 4.0 kPa";

(i) at page 22, lines 17-18, where the sentence "The Young's modulus of the cured polymer was measured by MFR as being 7.0 kPa" should read "The shear modulus of the cured polymer was measured by MFR as being 7.0 kPa".

I set out below my reasoning for this in context of the Present Application.

4. Elastic properties of a material (*i.e.*, "elastic modulus", "elasticity modulus" or "modulus of elasticity") may be determined by measuring rate of change of strain in the material as a function of stress applied to the material. (*See* EXHIBIT A, "Glossary of Materials Testing Terms, Modulus of Elasticity," also available from INSTRON Corporation at its website.) The elastic modulus may be reported in several ways including the shear modulus of elasticity, tensile modulus of elasticity, and compression modulus of elasticity. The equipment used to measure each type of modulus varies and is relevant to determining which modulus is measured. I set this out further below.

5. The modulus of the polymers of the Present Application was measured using a Micro Fourier Rheometer ("MFR"). An MFR is an instrument that was specially developed for characterisation of viscoelastic materials. It consists of a pair of surfaces or platens between which the material is placed. One platen applies an oscillatory shear stress to the material while the other measures the amplitude and phase of the oscillation transferred through the material. Fourier analysis is then used to calculate the modulus of the material.

6. When a material is tested on an MFR, one measure of the material's properties that can be obtained is the shear modulus. The shear modulus describes a material's response, in terms of a shear stress, to shearing strains. A shear stress is one where the stress is parallel or tangential to a face of the material. This is different to a normal stress where the stress is perpendicular to the face of the material.

7. Across the literature I have seen, shear modulus is also referred to as G', 'elastic modulus' (generically) and 'storage modulus', among other names. An MFR also measures a parameter referred to as G'' (which has various other names such as dynamic modulus, loss modulus, and viscous modulus) which is different from shear modulus.

8. The tensile modulus of elasticity is another modulus, which is different from the shear modulus of elasticity. A tensile modulus is measured by a tensile testing device (such as that manufactured by INSTRON Corporation). The tensile modulus describes a material's response, in terms of a tensile stress, to tensile strains. A tensile stress is a normal stress where the stress is perpendicular to the face of the material.

9. The tensile modulus is also referred to as 'E', 'E modulus', 'elastic modulus' (generically) and 'Young's modulus'.

10. The term 'elastic modulus' is therefore used to refer to both the shear modulus and the tensile modulus.

11. There are therefore overlapping terms and complexity surrounding the property of a material described as a modulus. When looking to determine what a publication is saying about a modulus (especially an elastic modulus), one typically looks to the method used to obtain the modulus results in addition to looking to the results themselves. In this way, one understands what was in fact measured, regardless of what it is called. For example, for a reference professing to report an elastic modulus (or indeed a shear modulus or tensile modulus), one would refer to the methods used to obtain the modulus as in doing so it would become clear exactly which modulus

was being reported. That is, if the methods describe the use of an MFR, one would understand that any modulus value reported was not E, Young's modulus or a compression modulus. Or, if the methods describe the use of an INSTRON device or similar, one would understand that any modulus value reported was actually a tensile modulus.

12. The moduli reported in the Present Applications were all measured on an MFR and are shear moduli (also generically referred to as elastic moduli). However, these moduli are incorrectly referred to in some places in the Present Application as "E modulus" or "Young's modulus" instead of any of the terms described above as being accurate references for shear moduli. However, on reading the method of measuring the modulus (*i.e.*, via an MFR), the fact that the reference to "E modulus" or "Young's modulus" is an obvious error and that the measurements are of shear modulus is readily apparent without reference to anything else. No other reasonable interpretation is possible.

13. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

By: _____

Timothy Charles Hughes

Date: 30th April 2008